## UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

	)	
AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
VS.	)	
	)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD;	)	
ROCHE DIAGNOSTICS GmbH; and	)	
HOFFMANN-LA ROCHE INC.	)	
	)	
Defendants.	)	
	)	

NOTICE OF FILING WITH CLERK'S OFFICE OF EXHIBITS TO DECLARATION OF KEITH E. TOMS IN SUPPORT OF DEFENDANTS' OPPOSITION TO AMGEN'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT OF '422 CLAIM 1, '933 CLAIM 3, AND '698 CLAIM 6

Pursuant to CMF/ECF Administrative Procedures Rule M(6) notice is hereby given that the exhibits listed below have been manually filed with the Court and are available in paper form only. The original documents are maintained in the case file in the Clerk's Office.

Exhibit 1	'178 File History, Application Claims at 49, 97, 101, 102.
Exhibit 2	'178 File History, Paper 11, 6/2/89 Amendment at 3-4.
Exhibit 3	'178 File History, Paper 13, 6/20/89 Office Action at 3, 5.
Exhibit 4	'178 File History, Paper 15, 7/11/89 Amendment at 1, 3-4.
Exhibit 5	'178 File History, Paper 17, 12/1/89 Examiner Interview Summary Record.
Exhibit 6	'178 File History, Paper 19, 1/10/90 Amendment at 1, 5, 6.
Exhibit 7	'178 File History, Paper 32, 4/21/99 Examiner Interview Summary.
Exhibit 8	'197 File History, Paper 35, Terminal Disclaimer.
Exhibit 9	'178 File History, Paper 4, 6/2/86 Office Action at 3-5.

- Exhibit 10 '178 File History, Paper 6, 12/1/88 Amendment and Reply at 3, 8-9.
- Exhibit 11 '178 File History, Paper 9, 2/10/89 Office Action.
- Exhibit 12 '179 File History, Paper 1.
- Exhibit 13 '179 File History, Paper 14, 9/27/88 Reply.
- Exhibit 14 '179 File History, Paper 29, 9/1/93 Office Action at 9-10.
- Exhibit 15 '179 File History, Paper 33, 1/3/94 Amendment and Response at 2, 5, 11.
- Exhibit 16 '179 File History, Paper 8, 5/24/88 Second Preliminary Amendment at 3-4, 6-10, 15-19.
- Exhibit 17 '197 File History, Paper 2, 11/6/90 Preliminary Amendment at 8.
- Exhibit 18 '197 File History, Paper 20, 6/1/94 Office Action at 3, 4.
- Exhibit 19 '197 File History, Paper 26, 3/31/95 Letter.
- Exhibit 20 '197 File History, Paper 33, 4/28/99 Amendment at 3-4.
- Exhibit 21 '197 File History, Paper 4, 4/6/92 Office Action at 2.
- Exhibit 22 '381 File History, Paper 1, Application.
- Exhibit 23 '381 File History, Paper 3a, 6/6/95 Continuing Application Transmittal.
- Exhibit 24 '381 File History, Paper 7, 12/11/96 Interview Summary.
- Exhibit 25 '381 File History, Paper 8, 12/20/96 Terminal Disclaimer;
- Exhibit 26 '381 File History, Paper 9, 12/20/96 Second Preliminary Amendment at 7-8, 10.
- Exhibit 27 '398 patent File History, Response to Final Office Action and Amendment (6/24/02) at 5.
- Exhibit 28 '741 File History, Application Claims at 102.
- Exhibit 29 '741 File history, Paper 1, 11/6/90 Application.
- Exhibit 30 '741 File History, Paper 2, 11/6/90 Preliminary Amendment at 2, 4, 5, 6 and 8.
- Exhibit 31 '741 File History, Paper 4, 4/6/92 Office Action.
- Exhibit 32 '774 File History, Paper 45, 6/7/95 Preliminary Amendment at 2.
- Exhibit 33 '774 File History, Paper 50, 12/20/95 Second Preliminary Amendment at 2.

Exhibit 34 '874 File History, Paper 37, 6/13/94 Preliminary Amendment.

Exhibit 35 '197 File History, Paper 23, 12/1/94 Request for Reconsideration.

Exhibit 36 '197 File History, Paper 25, 3/3/95 Amendment and Declaration of Richard D. Cummings, Ph.D.

Exhibit 37 12/20/99 Expert Statement of Harvey F. Lodish, Ph.D., at paragraph 124.

Exhibit 38 is intentionally omitted.

Exhibit 39 is intentionally omitted.

Exhibit 40 4,703,008.

Exhibit 41 is intentionally omitted.

Exhibit 42 5,153,265.

Exhibit 43 5,441,868.

Exhibit 44 5,547,933.

Exhibit 45 5,618,698.

Exhibit 46 5,856,298.

Exhibit 47 5,955,422.

Exhibit 48 5/11/07 Cords Report ¶¶ 24-33.

Exhibit 49 6,399,333.

Exhibit 50 6,471,500.

Exhibit 51 6,583,272.

Exhibit 52 6,586,398.

Exhibit 53 7,217,689.

Exhibit 54 is intentionally omitted.

Exhibit 55 is intentionally omitted.

Exhibit 56 Abuchowski et al. (1977) at 3579.

Exhibit 57 Alberts (1983) at 92.

Exhibit 58 AM 44 0004799-834 at 809.

- Exhibit 59 AM 44 0197792.
- Exhibit 60 AM 44 0445251-5274 at 61.
- Exhibit 61 AM44 0003879.
- Exhibit 62 AM44 0004809.
- Exhibit 63 AM44 004799-AM44 0004834: "How Do Physical Changes in ESPs Affect Biological Activity".
- Exhibit 64 AM44 0156801-0156884 at 811.
- Exhibit 65 AM44 0230737-67 at 745.

Exhibit 66 is intentionally omitted.

- Exhibit 67 AM44 0825645.
- Exhibit 68 AM44 0897376-82.
- Exhibit 69 AM44 1591670-1679.
- Exhibit 70 AM67 01078325-330 at 327.
- Exhibit 71 is intentionally omitted.
- Exhibit 72 Amgen I at 91.
- Exhibit 73 Amgen Inc.'s Response to Defendants' Claim Construction Brief filed 3/19/07 323.
- Exhibit 74 AM-ITC 00974613 (Amgen Patent Tree).
- Exhibit 75 Amgen Supplemental Response to Rogg. 8, 2/10/07.
- Exhibit 76 *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 283-303 (D. Mass. 2004).
- Exhibit 77 Amgen's Epogen Label.
- Exhibit 78 Amgen's Supp. Response to Rogg 8, dated 2/9/07 at 26.
- Exhibit 79 AM-ITC 00052992-95.
- Exhibit 80 AM-ITC 00102090-105.
- Exhibit 81 AM-ITC 00595293.

- Exhibit 82 AM-ITC 00596039-042.
- Exhibit 83 AM-ITC 00941090-1099, at 1094.
- Exhibit 84 AM-ITC-00087147-7158.
- Exhibit 85 AM-ITC-00900034-39.
- Exhibit 86 AM-ITC-00903447-56.
- Exhibit 87 AM-ITC-00929860-862.
- Exhibit 88 AM-ITC-01072476-2501.
- Exhibit 89 AM-ITC 00592757.
- Exhibit 90 Banga (2006) at 205.
- Exhibit 91 Beauchamp et al. (1983) at 31.
- Exhibit 92 Benet Report I ¶¶ 30-32.
- Exhibit 93 Benet Tr. 197:7-15, 246:11-13.
- Exhibit 94 Boone Tr. (3/30/07) 28:11-22, 31:5-12, 46:20-22, 93:1-10, 94:21-95:4, 96:12-21 24:22-26:1, 31:6-11, 46:20-22, 76:6 77:16, 92:24 93:3, 94:14 96:24, 159:16-24.
- Exhibit 95 Bradshaw Expert Report 6/1/07 ¶¶ 17, 20.
- Exhibit 96 Bradshaw Tr. pp. 272:20-277:18, 76:2-10, 16:1-25.
- Exhibit 97 Cheetham et al. (1998) at 861.
- Exhibit 98 is intentionally omitted.
- Exhibit 99 Cram & Cram, "The Essence of Organic Chemistry" 273 (Addison-Wesley Publishing Co. 1978)).
- Exhibit 100 Declaration of Thomas Wayne Strickland (11/30/88 ¶ 5, 6, 11).
- Exhibit 101 Delgado (1992) at 274, 276.
- Exhibit 102 Delivery of Protein and Peptide Drugs in Cancer (2006) Chapter 4 pp. 76-77.
- Exhibit 103 Delorme et al. (1992).
- Exhibit 104 Elliot Tr., 3/29/07, pp. 198:12-199:11.

- Exhibit 105 is intentionally omitted.
- Exhibit 106 Elliott Depo. Tr. (5/20/98) Ortho Biotech v. Kirin-Amgen, 70:22-72:15, 141:6-141:9).
- Exhibit 107 Elliott et al., *Mapping of the Active Site of Recombinant Human Erythorpoietin*, Blood, Vol. 89, No. 2, pp. 493-502 (1997)).
- Exhibit 108 Elliott *Ortho* Tr. 10/15/98 at 3354:22-3355:17, 3421:8-3424:20, 3636:1-10.
- Exhibit 109 Elliott Tr. (3/29/07) 13:5-16; 23:16-19; 24:13-15; 24:23-25:2, 201:25-202:22, 216:16-220:12, 229:4-232:21, 237:13-241:24.
- Exhibit 110 Elliott, S.G., New Molecules and Formulations of Recombinant Human Erythropoietin, *in* ERYTHROPOIETINS AND ERYTHROPOIESIS 241-58 (G. Molineux et al., eds. 2003)).
- Exhibit 111 EPOGEN Label issued 03/09/07 p. 25.
- Exhibit 112 is intentionally omitted.
- Exhibit 113 Exhibit 31 to its "Memorandum In Support of Amgen Inc.'s Motion for Summary Judgment Of Infringement of '422 Claim 1, '933 Claim 3, And '698 Claim 6.".
- Exhibit 114 File History of U.S. Pat. No. 4,703,008, AM-ITC-00873591.
- Exhibit 115 Genentech, Inc., v. Boehringer Mannheim Gmbh, 47 F.Supp.2d 91, 95 (D. Mass. 1999.
- Exhibit 116 Goldwasser et al. (1974) at 4202-4206.
- Exhibit 117 Goldwasser Tr. 2/14/07, pp. 177:18-178:11).
- Exhibit 118 Gross & Lodish (2006) Entire Article.
- Exhibit 119 Gutfreund (1955).
- Exhibit 120 Halstenson Clin. Pharmacol. Ther. 50: 702-712 (1991).
- Exhibit 121 Harris & Chess (2003) at 215, 220.
- Exhibit 122 Harris (2001), 542-549).
- Exhibit 123 Haselbeck Dep. Tr. 128-129.
- Exhibit 124 Heatherington *in* ERYTHROPOIETINS AND ERYTHROPOIESIS AT 87 (G. Molineaux et al., eds. 2003)0.
- Exhibit 125 http://www.amgen.com/patients/prca.html.

- Exhibit 126 Hynes, Adherence to Guidelines for ESRD Anemia Management 2006.
- Exhibit 127 ITC-R-BLA-00005515.
- Exhibit 128 ITC-R-BLA 00000091.
- Exhibit 129 ITC-R-BLA- 00004032, 4035.
- Exhibit 130 ITC-R-BLA- 00004271-4275.
- Exhibit 131 ITC-R-BLA- 00004301-4306.
- Exhibit 132 ITC-R-BLA- 00005580.
- Exhibit 133 ITC-R-BLA 00007306-00007318.
- Exhibit 134 AM-ITC 00899473.
- Exhibit 135 ITC-R-BLA-00004178.
- Exhibit 136 ITC-R-BLA-0000001-22.
- Exhibit 137 ITC-R-BLA-00000066 (draft package insert).
- Exhibit 138 ITC-R-BLA-00000212.
- Exhibit 139 ITC-R-BLA-00000217.
- Exhibit 140 ITC-R-BLA-00000248.
- Exhibit 141 ITC-R-BLA-00000250.
- Exhibit 142 ITC-R-BLA-00000261.
- Exhibit 143 ITC-R-BLA-00000309.
- Exhibit 144 ITC-R-BLA-00000313-327.
- Exhibit 145 ITC-R-BLA-00000322-325.
- Exhibit 146 ITC-R-BLA-00000502-506, 511-513.
- Exhibit 147 ITC-R-BLA-00002808.
- Exhibit 148 ITC-R-BLA-00003366.
- Exhibit 149 is intentionally omitted.
- Exhibit 150 ITC-R-BLA-00003417.

- Exhibit 151 ITC-R-BLA-00003428-29.
- Exhibit 152 ITC-R-BLA-00004027.
- Exhibit 153 ITC-R-BLA-00004028.
- Exhibit 154 ITC-R-BLA-00004029.
- Exhibit 155 ITC-R-BLA-00004031.
- Exhibit 156 ITC-R-BLA-00004032.
- Exhibit 157 ITC-R-BLA-00004035.
- Exhibit 158 ITC-R-BLA-00004043.
- Exhibit 159 ITC-R-BLA-00004046-4051.
- Exhibit 160 ITC-R-BLA-00004059.
- Exhibit 161 ITC-R-BLA-00004126.
- Exhibit 162 ITC-R-BLA-00004178.
- Exhibit 163 ITC-R-BLA-00004233.
- Exhibit 164 ITC-R-BLA-00004241-4268.
- Exhibit 165 ITC-R-BLA-00004247-4256.
- Exhibit 166 ITC-R-BLA-00004257-4268.
- Exhibit 167 ITC-R-BLA-00004271-4275.
- Exhibit 168 ITC-R-BLA-00004296-4316.
- Exhibit 169 ITC-R-BLA-00004299-300.
- Exhibit 170 ITC-R-BLA-00004307-4312.
- Exhibit 171 ITC-R-BLA-00004659.
- Exhibit 172 ITC-R-BLA-00004660.
- Exhibit 173 ITC-R-BLA-00004661.
- Exhibit 174 ITC-R-BLA-00004663-4.
- Exhibit 175 ITC-R-BLA-00004667.

- Exhibit 176 ITC-R-BLA-00004680.
- Exhibit 177 ITC-R-BLA-00004682-4704.
- Exhibit 178 ITC-R-BLA-00004716.
- Exhibit 179 ITC-R-BLA-00004722.
- Exhibit 180 ITC-R-BLA-00004723.
- Exhibit 181 is intentionally omitted.
- Exhibit 182 is intentionally omitted.
- Exhibit 183 ITC-R-BLA-00005616-32.
- Exhibit 184 ITC-R-BLA-00005656-74.
- Exhibit 185 ITC-R-BLA-00005770-73.
- Exhibit 186 ITC-R-BLA-00007081-7124.
- Exhibit 187 ITC-R-BLA-00007125-7158 Entire Doc.
- Exhibit 188 ITC-R-BLA-00007159-7206.
- Exhibit 189 ITC-R-BLA-00007243-255.
- Exhibit 190 is intentionally omitted.
- Exhibit 191 ITC-R-BLA-00007256-70.
- Exhibit 192 ITC-R-BLA-00007267.
- Exhibit 193 ITC-R-BLA-00007271-90.
- Exhibit 194 ITC-R-BLA-00007281-3, Figures 1 and 2.
- Exhibit 195 ITC-R-BLA-00007291-7305.
- Exhibit 196 ITC-R-BLA-00007310-18 at 15-18, figs. 1 and 2, table 1.
- Exhibit 197 ITC-R-BLA-00007319- 753 at 325, Fig.1, Tables 1 and 2; 326-327, Fig. 2, Tables 3 and 4.
- Exhibit 198 ITC-R-BLA-00007469-7506 at 7486, 7490.
- Exhibit 199 ITC-R-BLA-00019402-84.
- Exhibit 200 is intentionally omitted.

- Exhibit 201 is intentionally omitted.
- Exhibit 202 ITC-RBLA-00022202-00022327.
- Exhibit 203 ITC-R-BLA-0005775-81.
- Exhibit 204 ITC-R-BLA-00066252-66426 at 282.
- Exhibit 205 ITC-R-BLA-00075601-802.
- Exhibit 206 ITC-R-BLA-00084420-84557.
- Exhibit 207 ITC-R-BLA-00109530-675.
- Exhibit 208 ITC-R-BLA-00115298-421.
- Exhibit 209 ITC-R-BLA-00140975-41134.
- Exhibit 210 is intentionally omitted.
- Exhibit 211 ITC-R-IND-00064970-981 at 971.
- Exhibit 212 Jacobs 1985.
- Exhibit 213 Jarsch (3/27/07) Tr. at 56:8-17.
- Exhibit 214 Jorgensen and Tirado-Rives Molecular Modeling of Organic and Biomolecular Systems Using BOSS and MCPRO, Comput. Chem. 2005, 26, 1689-1700.
- Exhibit 215 Karp (2002) at 52-53, 55-62.
- Exhibit 216 Katre (1993) at 93, 95, 98, 103.
- Exhibit 217 Kinstler et al. (2002) at 478.
- Exhibit 218 Klibanov 5/11/07 Expert Report ¶ 116.
- Exhibit 219 Klibanov Tr. 5/23/07. 153:18-154:13.
- Exhibit 220 Kozlowski and Harris (2001) at 219-20.
- Exhibit 221 Krantz and Goldwasser, Specific Binding of Erythropoietin to spleen cells infected with the anemia strain of Friend virus, Proc. Natl. Acad. Sci, 81: 7574-7578 (1984).
- Exhibit 222 Kynclova (1996) at 644.
- Exhibit 223 Lai 1986.

- Exhibit 224 Lin *et al.*, "Cloning and expression of the human erythropoietin gene," *PNAS*, 82 7580-7584 (1985).
- Exhibit 225 Lin Tr. (3/28/07) 91:4-122:25, 304:12-305:5.
- Exhibit 226 Lin Tr. 6/7/00 at 965:8-14.
- Exhibit 227 Lodish 4/6/07 Expert Report ¶¶ 24, 31-33, 92, 94-95, 139, 141, 172, 182, 183, 187-89, 192.
- Exhibit 228 Lodish Dep. Tr., J&J Arb., Jul. 30, 1998 at 110-111.
- Exhibit 229 Macdougall & Eckardt, "Novel strategies for stimulating erythropoiesis and potential new treatments for anaemia," Lancet, 2006, 368:947-953).
- Exhibit 230 MacDougall (2005) at 436, 439.
- Exhibit 231 Macdougall Clin J. Am Soc. Nephrol. 1: 1211-1215 (2006).
- Exhibit 232 Macdougall J. Am Soc Nephrol 10: 2392-2395 (1999).
- Exhibit 233 Markman Tr.
- Exhibit 234 Mattison (2001) at 66-67.
- Exhibit 235 Mayeux, P. et al., *The Erythropoietin Receptor of Rat Erythroid Progenitor Cells; Characterization and Affinity Cross Linkage*, J. Bio. Chem., Vol. 262, No. 29, pp. 13985-13990 (1987)).
- Exhibit 236 Molineux (2002) at 13-15.
- Exhibit 237 Molineux Depo. Tr., 3/28/07 at 44-45, 47-48.
- Exhibit 238 Molineux in "Erythropoietins and Erythropoiesis, Molecular, Cellular, Preclinical and Clinical Biology" at 8, fig. 2).
- Exhibit 239 Molineux Tr. (3/28/07) 43:19-50:6, 72:1- 72:20.
- Exhibit 240 Molineux, Anti-Cancer Drugs (2003) at 259-260.
- Exhibit 241 Molineux, Pharmacotherapy (2003) at 5S.
- Exhibit 242 Morrison & Boyd (1983) at 2-3, 79, 157.
- Exhibit 243 MPEP §2173.05(p) (8<sup>th</sup> ed. Rev. 5, Aug. 2006).
- Exhibit 244 MPEP §706.03(e) (5<sup>th</sup> ed. Rev. 6, Oct. 1987).
- Exhibit 245 is intentionally omitted.

- Exhibit 246 Ossulund (2003) at 32-33.
- Exhibit 247 R001507222-225.
- Exhibit 248 R001564952-981 at 960.
- Exhibit 249 R001572230.
- Exhibit 250 R004792356.
- Exhibit 251 R004961456.
- Exhibit 252 R005310871.
- Exhibit 253 R005312429-2430.
- Exhibit 254 R005312436.
- Exhibit 255 R005312471.
- Exhibit 256 R005312683-774.
- Exhibit 257 R008890740-755.
- Exhibit 258 R-10-002641295.
- Exhibit 259 R11-000165902.
- Exhibit 260 R11-000636121-129.
- Exhibit 261 Rawn BIOCHEMISTRY (1989) at 106).
- Exhibit 262 Recny *et al.*, "Structural Characterization of Natural Human Urinary and Recombinant DNA-derived Erythropoietin," *J. Biol. Chem.*, 262(35) 17156-17163 (1987) at 17161.
- Exhibit 263 Roberts et al. (2002) at 462, 474.
- Exhibit 264 Schneider, Homodimerization, 1997;.
- Exhibit 265 Stewart (1959).
- Exhibit 266 Storring et al., (1998) 100: 79-89.
- Exhibit 267 Strickland Tr. (3/9/07).
- Exhibit 268 Stryer (1988) at 4.
- Exhibit 269 is intentionally omitted.

- Exhibit 270 Syed (1998) at 515.
- Exhibit 271 is intentionally omitted.
- Exhibit 272 Torchilin 4/6/07 Expert Report ¶¶ 61, 86-88,110.
- Exhibit 273 Torchilin 6/1/07 Expert Report ¶¶ 14, 30, 41, 51).
- Exhibit 274 Torchilin Dep. Tr. 06/18/07 at.
- Exhibit 275 U.S.S.N. 06/866,459.
- Exhibit 276 U.S.S.N. 07/632,070, Paper No. 15, dated December 2, 1991, p.13.
- Exhibit 277 U.S.S.N. 07/983,620, Paper No. 27, dated August 13, 1996, p. 8.
- Exhibit 278 U.S.S.N. 08/413,803, Paper No. 12, dated December 10, 1996, p. 14.
- Exhibit 279 U.S.S.N. 08/479,892, "Brief for Party Elliott" dated February 11, 2004.
- Exhibit 280 USSN 06/866,459, Paper No. 5, dated 8/3/87, pp. 4-7, 9, 10.
- Exhibit 281 is intentionally omitted.
- Exhibit 282 Varki I at para. 86, 89, 92.
- Exhibit 283 Veronese (1985) at 142.
- Exhibit 284 Veronese et al. (1983) at 757.
- Exhibit 285 I TC-R-BLA-00004026.
- Exhibit 286 Bailon & Berthold, "Polyethylene glycol-conjugated pharmaceutical proteins," PSTT 1(8): 352-356 (1998).
- Exhibit 287 Meister (ed). Biochemistry of the Amino Acids Volume 1.
- Exhibit 288 CKD Best Practice September/October 2004.
- Exhibit 289 Morgan Stanley Equity Research AMGEN: Some Setbacks For Competitors In EU, February 23, 2006.
- Exhibit 290 Pollack, A., "Rivals Laying Siege to Amgen's Near Monopoly in Anemia Drugs," The New York Times, Dec. 23, 2005.
- Exhibit 291 Memo in Support of Roche's Motion for Summary Judgment of Non-Infringement of Claim 1 of Patent No. 5,955,422.

Exhibit 292 Memo in Support of Roche's Motion for Summary Judgment of Non-Infringement that Claims of the '933 Are Invalid for Indefiniteness and Lack of Written Description.

Exhibit 293 Torchilin II expert report ¶ 66.

Exhibit 294 the Widness and Veng-Pedersen Report.

Exhibit 295 the Supplemental Expert Report of Harvey F. Lodish

Dated: June 29, 2007

Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE INC.

By its attorneys,

## /s/ Julia Huston

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## **CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on the above date.

/s/ Julia Huston Julia Huston

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